

Claims

1. A process for making a polymeric product having a gradual variation in modulus through at least a portion of the product, comprising the steps of:
 - 5 (a) reacting a multifunctional isocyanate, a polyol and, optionally, a chain extender, wherein at least two reagents selected from the isocyanate, the polyol, the chain extender, any mixture thereof and any pre-polymer formed therefrom, are intensively mixed to form a first polyurethane having a predetermined stoichiometry and thermal history;
 - 10 (b) reacting a multifunctional isocyanate, a polyol and, optionally, a chain extender, wherein at least two reagents selected from the isocyanate, the polyol, the chain extender, any mixture thereof and any pre-polymer formed therefrom, are intensively mixed to form a second polyurethane having a predetermined stoichiometry and thermal history which is different to the stoichiometry and
15 thermal history of the first polyurethane; and
 - (c) injecting the first and second polyurethanes into a mould defining the polymeric product before the polymerisation reactions associated with the production of the first and second polyurethanes are complete so that polymerisation reactions between the first and second polyurethanes occur in the mould.
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2. A process according to claim 1, comprising the step of injecting the first and second polyurethanes into the mould simultaneously.
3. A process according to claim 2, comprising the step of altering the relative
25 rate of injection of the first polyurethane into the mould relative to the rate of injection of the second polyurethane into the mould.
4. A process according to claim 1, including the step of mixing the first and second polyurethanes prior to injection into the mould via a common injection port.
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5. A process according to claim 4, including the step of altering the length of the common injection port to control the degree of mixing of the first and second polyurethanes prior to injection into the mould.

6. A process according to any preceding claim comprising the step of controlling the relative amounts of the first and second polyurethanes injected into the mould.
- 5 7. A process according to claim 6, including the step of injecting the same amount of the first and second polyurethanes into the mould.
8. A process according to any preceding claim, wherein the method includes
10 the step of forming the first and second polyurethanes simultaneously in a separate apparatus.
9. A process according to any of claims 1 to 8, wherein the method includes the step of forming the first and second polyurethanes using the same apparatus, the
15 method comprising the steps of forming the first polyurethane and subsequently perturbing the relative amounts of the reagents to form the second polyurethane.
10. A process according to claim 9, including the step of passing the first polyurethane into an intermediate vessel before formation of the second
20 polyurethane.
11. A process according to claim 10, wherein the method includes the step of passing the second polyurethane into an intermediate vessel.
- 25 12. A process according to claim 10, including the step of simultaneously injecting the first and second polyurethanes into the mould from said intermediate vessels.
13. A process according to claim 11, including the step of injecting the first and
30 second polyurethanes into the mould at different injection rates.
14. A process according to any of claims 10 to 13, wherein the method includes the step of controlling the temperature of the or each intermediate vessel to impart

a different stoichiometry and/or thermal history to the first and second polyurethanes contained therein.

15. A process for making a polymeric product having a gradual variation in modulus through at least a portion of the product comprising the steps of:
- 5 (a) reacting a multifunctional isocyanate, a polyol and, optionally, a chain extender, wherein at least two reagents selected from the isocyanate, the polyol, the chain extender, any mixture thereof and any pre-polymer formed therefrom, are intensively mixed to form a polyurethane having a predetermined stoichiometry and
- 10 thermal history;
- (b) continuously perturbing the relative amounts of said at least two reagents during the course of the reaction to continuously vary the modulus of the polyurethane so formed and,
- (c) injecting the polyurethane into a mould defining the polymeric product before
- 15 the polymerisation reactions associated with the production of the polyurethane is complete so that polymerisation continues in the mould.
16. A process according to any preceding claim, wherein the polyurethane is passed through an extruder to be reactively extruded therein.
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17. A process according to claim 16, wherein the polyurethane undergoes thermal profiling during the reactive extrusion step.
18. An artificial spinal disc comprising a solid body of polymeric material that
- 25 exhibits at least a portion having a gradual variation in modulus.
19. An artificial spinal disc according to claim 18, wherein the modulus varies substantially linearly through said portion.
- 30 20. An artificial spinal disc according to claim 18 or 19, comprising a nucleus surrounded by an annulus region, said portion being located in a region between the nucleus and annulus regions.

21. An artificial spinal disc according to any of claims 18 to 20, including a pair of integral polymeric end plates configured such that there are no interfacial bonds between the end-plates and the remainder of the spinal disc.
- 5 22. An artificial spinal disc according to any of claims 18 to 21, manufactured according to the process of any of claims 1 to 17.
23. A surgical implant manufactured according to the process of any of claims 1 to 17.
- 10 24. Apparatus for making a polymeric product having a gradual variation in modulus through at least a portion of the product comprising:
- (a) a first delivery system for quantitatively dispensing at least two reagents selected from an isocyanate, a polyol, a chain extender, any mixture thereof and any pre-
- 15 polymer formed therefrom; mixing means for intensively mixing said at least two reagents to form a first polyurethane having a predetermined stoichiometry.
- (b) a second delivery system for quantitatively dispensing at least two reagents selected from an isocyanate, a polyol, a chain extender, any mixture thereof and any pre-polymer formed therefrom; mixing means for intensively mixing said at least
- 20 two reagents and reactive extrusion means to form a second polyurethane having a different predetermined stoichiometry to that of the first polyurethane, and
- (c) means for injecting the first and second polyurethanes into a mould before the polymerisation reactions associated with the formation of the first and second polyurethanes are complete so that polymerisation reactions between the first and
- 25 second polyurethanes occur in the mould.
25. Apparatus for making a polymeric product having a gradual variation in modulus through at least a portion of the product comprising:
- (a) a delivery system for quantitatively dispensing at least two reagents selected from
- 30 an isocyanate, a polyol, a chain extender, any mixture thereof and any pre-polymer formed therefrom; mixing means for intensively mixing said at least two reagents to form a first polyurethane having a predetermined stoichiometry.

(b) an intermediate vessel into which the first polyurethane is directed whilst the delivery system is used to quantitatively dispense at least two reagents selected from an isocyanate, a polyol, a chain extender, any mixture thereof and any pre-polymer formed therefrom; mixing means for intensively mixing said at least two reagents
5 and reactive extrusion means to form a second polyurethane having a different predetermined stoichiometry to that of the first polyurethane, and
(c) means for injecting the first and second polyurethanes into a mould before the polymerisation reactions associated with the formation of the first and second polyurethanes are complete so that polymerisation reactions between the first and
10 second polyurethanes occur in the mould.

26. Apparatus according to claim 25, including a second intermediate vessel into which the second polyurethane is directed so that the first and second polyurethanes are injected from their respective vessels into the mould.

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27. Apparatus according to claim 25 or 26, including a common injection port for injecting the first and second polyurethanes into the mould simultaneously.

28. Apparatus according to claim 27, comprising means for mixing the first and
20 second polyurethanes prior to injection into the mould.

29. Apparatus according to any of claims 26 to 28, including means for varying the relative amounts of the first and second polyurethanes injected into the mould or, the relative rates of injection of the first and second polyurethanes into the
25 mould.

30. An artificial spinal disc manufactured using the apparatus according to any of claims 24 to 29.

30 31. Use of the process according to any of claims 1 to 17, for the manufacture of an artificial spinal disc.

32. Use of the process according to any of claims 1 to 17, for the manufacture of a surgical device.